REMARKS

Claims 1-3, 5-15 and 17-86 are pending and under examination. Claims 29-62 and 77-84 have been canceled. Claims 1, 15, 17-19, 24-28, 63, 64, 85 and 86 have been amended as set forth above in the Listing of Claims. Claim 1, 15, 24-28, 63, 64, 85 and 86 has been amended to recite that particular tissues. Support for the amendments to claims can be found throughout the original specification. Claims 17-19 have been corrected to reflect dependency on the proper base claim. The amendments do not introduce any Previously presented matter and entry of the amendments is respectfully requested. Upon entry of the amendments, claims 1-3, 5-15, 17-28, 63-76, 85 and 86 will be pending and under consideration.

Regarding 35 U.S.C. §112, First Paragraph

The objection to the specification and corresponding rejection of claims 1-3, 5-15, 17-28 and 63-86 under 35 U. C. 112 , first paragraph, for allegedly lacking an enabling disclosure is respectfully rejected. This rejection is rendered moot as to claims 77-84, which have been canceled herein.

The Office Action maintains, beginning at page 4, that the specification , while being enabling for an *in vitro* method of acceleration of the cell cycle in fibroblasts using radio frequency radiation, *in vitro* method of activation of a cell cycle regulator, a signal transduction protein , a transcription factor, a DNA synthesis protein and a receptor in fibroblasts keratinocytes using radio frequency radiation , does not reasonably provide enablement for an the corresponding *in vivo* methods.

Rejecting Applicants' previous arguments, the Examiner now cites *In re Gardner, Roe and Willey, 427 F.2d 786, 789 (C.C.P.A. 1970)* for the proposition that the law requires Applicants' close how to use the claimed invention. The Gardner case involved disclosure of rat dosages to enable treatment in humans and enablement was lacking because the court found that human doses are likely to vary hugely from effective doses in rats. Rats are not accepted models for correlating human dosages. On the other hand, the Simko and Mattson reference cited in the present Office Action clearly confirms that *in vitro* results are accepted in the art as reasonably correlating to *in vivo* results by using the *in vitro* data regarding cellular changes in response to

electromagnetic field exposure as a basis to draw a variety of conclusion about *in vivo* effects and should be accepted as evidence for the enablement of the *in vivo* embodiments of the invention. More on point than *Gardner*, the case cited by In *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 47 U.S.P.Q.2d 1705 (Fed. Cir. 1998), the Federal Circuit clearly stated that routine experimentation does not constitute undue experimentation:

> The test [for undue experimentation] is not merely quantitative, since **a considerable amount of experimentation is permissible**, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed.

Id. (Emphasis added) (citing *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d at 1564, 37 U.S.P.Q.2d at 1623); see also *In re Wands*, 858 F.2d at 736-40, 8 U.S.P.Q.2d at 1403-07.

For the reasons set forth in Applicants' previous response, it is submitted that the cited references confirm that the enabled *in vitro* working examples are recognized by those skilled in the art as correlating to *in vivo* conditions. The Office now cites passages of these references that imply that some experimentation may be necessary by the skilled person to practice the methods. If this is the case, it does not defeat enablement nor does it change the fact that the references confirm the art acceptance of in vitro results as correlating to in vivo results. Unless the Office produces particular evidence to the contrary, the acknowledgement that *in vitro* methods are enabled, should be accepted as evidence for the enablement of the *in vivo* embodiments of the invention.

In view of the extensive teachings and working examples as previously discussed on the record; the Office's acknowledgement that the *in vitro* methods are enabled and the evidence those skilled in the art accepted the correlation between *in vitro* and *in vivo* results for the claimed methods, it is respectfully submitted that the enablement rejection is not properly supported. Accordingly, Applicants respectfully request withdrawal of the objection to the specification and removal of the corresponding rejection of claims 1-3, 5-15, 17-28 and 63-86 under 35 U. C. 112 , first paragraph, for allegedly lacking an enabling disclosure.

Regarding 35 U.S.C. § 102

When lack of novelty is based on a printed publication that is asserted to describe the same invention, a finding of anticipation requires that the publication describe all of the elements of the claims. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1349, 48 U.S.P.Q.2d 1225, (Fed.

Cir. 1998) (quoting *Shearing v. Iolab Corp.*, 975 F.2d 1541, 1544-45, 24 U.S.P.Q.2d 1133, 1136 (Fed. Cir. 1992)). To establish a *prima facie* case of anticipation, the Office must show that the single reference cited as anticipatory art describes all the elements of the claimed invention.

George et al., U. S. Patent No. 6,334,069

The rejection of claims 1-3, 5-13, 15, 17-24, 63-72 and 77-86 under 35 U.S.C. §102(b) as being anticipated by George et al (U. S. Patent No. 6,334;069, 12/25/2001) is respectfully traversed. Without conceding that there is any merit to the instant rejection, Applicants submit that the rejection is rendered moot by the amendments to the claims proposed above. Accordingly, removal of the rejection is respectfully requested.

George et al., U. S. Patent No. 6,353,763

The rejection of claims 1-3, 5-13, 15, 17-24, 63-72 and 77-86 under 35 U.S.C. §102(a) as being anticipated by George et al (U. S. Patent No. 6,353,763, 3/5/2002). Without conceding that there is any merit to the instant rejection, Applicants submit that the rejection is rendered moot by the amendments to the claims proposed above.. Accordingly, removal of the rejection is respectfully requested.

The rejection of claims 1-3, 5-13, 15, 17-24, 63-72 and 77-86 under 35 U.S.C. §102(e) as being anticipated by George et al (U. S. Patent No. 6,353,763, 3/5/2002) is respectfully traversed. Without conceding that there is any merit to the instant rejection, Applicants submit that the rejection is rendered moot by the amendments to the claims proposed above. Accordingly, removal of the rejection is respectfully requested.

George et al., U. S. Patent No. 7,024,239

The rejection of claims 1-3, 5-13, 15, 17-24, 63-72 and 77-86 under 35 U.S.C. §102(e) as being anticipated by George et al (U. S. Patent No. 7,024,239 , filed 11/20/2001) is respectfully traversed. Without conceding that there is any merit to the instant rejection, Applicants submit that the rejection is rendered moot by the amendments to the claims proposed above. Accordingly, removal of the rejection is respectfully requested.

Yarosh, U. S. Patent No, 5,352,458

The rejection of claim 26 under 35 U.S.C. §102(b) as being anticipated by Yarosh (U.S. Patent No, 5,352,458) is respectfully traversed. Without conceding that there is any merit to the instant rejection, Applicants submit that the rejection is rendered moot by the amendments to the claims proposed above. Accordingly, withdrawal of the rejection of claim 26 under 35 U.S.C. §102(b) as being anticipated by Yarosh (U.S. Patent No, 5,352,458) is respectfully requested.

Derijard et al., Cell 76:1025-1037

The rejection of claim 24 under 35 U.S.C. §102(b) as being anticipated by Derijard et al., *Cell* 76:1025-1037 is respectfully traversed. Without conceding that there is any merit to the instant rejection, Applicants submit that the rejection is rendered moot by the amendments to the claims proposed above. Accordingly, withdrawal of the rejection of claim 26 under 35 U.S.C. §102(b) as being anticipated by Derijard et al., *Cell* 76:1025-1037, is respectfully requested.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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